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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,281	02/20/2002	Wayne Kindsvogel	014058-005631US	6456

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EXAMINER
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VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/081,281

### Applicant(s)

KINDSVOGEL ET AL.

### Examiner

F. Pierre VanderVegt

### Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39,41,42,44-46 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39,41,42,44-46 and 50-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number 09/261,811, which is a continuation of U.S. Application Serial Number 08/657,581, and is a continuation-in-part of U.S. Application Serial Number 08/480,002, and is a continuation-in-part of U.S. Application Serial Number 08/483,241, and is a continuation of U.S. Application Serial Number 08/482,133, and claims the benefit of the filing date of provisional application 60/005,964.

Claims 1-38, 40, 43 and 47-49 have been canceled.

Claims 50-54 have been added.

Claims 39, 41, 42, 44-46 and 50-54 are currently pending and are the subject of examination in the present Office Action.

### ***Response to Arguments***

1. In view of Applicant's amendment filed October 14, 2003 all previous grounds of rejection are withdrawn. The following represents a new ground of rejection.
2. Applicant's arguments with respect to claims 39, 41, 42, 44-46 and 50-54 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 39, 41, 42, 44-46 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Applicant has amended base claim 39 to recite “a first nucleic acid segment encoding a first polypeptide segment comprising an  $\beta 1\beta 2$  domain of an MHC class II chain molecule” in subsection (b) (i) of the claim. The recitation of a  $\beta 1\beta 2$  domain is not supported in the specification or claims as originally filed. The specification and claims as originally filed disclose only:

- a first polypeptide segment [S1] consisting essentially of a first DNA segment encoding at least a portion of a first domain of a selected MHC molecule (page 4, lines 27-29 for example), wherein that first domain can be a class II (page 5, lines 9-10 for example) that can be a  $\beta 1$  domain (page 5, lines 11-12 for example)
- joined by a linker [L1] of 5-25 amino acids (page 4, lines 31-32 for example)
- to a second DNA segment [S2] encoding at least a portion of a second segment of the selected MHC molecule (page 4, lines 29-31 for example), wherein that second segment can be a  $\alpha 1$  domain or  $\alpha 1\alpha 2$  domains (page 5, lines 13-14 for example)
- joined by a linker [L2] of 5-25 amino acids (page 4, lines 31-32 for example)
- to a third DNA segment [S3] which encodes an associated antigenic peptide (page 4, lines 36-37 for example).

Embodiments of the invention are also disclosed to include:

- a fourth DNA segment [S4] that is a  $\beta 2$  chain (page 6, lines 10-11 for example).

The specification further discloses that the segments, when including the segment that is a  $\beta 2$  chain, "comprises a fourth DNA segment encoding at least a portion of a third domain of the selected MHC molecule, and a third linker [L3] DNA segment encoding about 5 to about 25 amino acids and connecting in-frame the second and fourth DNA segments resulting in a fused third DNA-second linker-first DNA-first linker-second DNA-third linker-fourth DNA polysegment" (page 7, lines 4-12 for example), resulting in the configuration:

S3-L2-S1-L1-S2-L3-S4.

In order for claim 39 to have written descriptive support for the recitation of “a first nucleic acid segment encoding a first polypeptide segment comprising an  $\beta 1\beta 2$  domain of an MHC class II chain molecule” the specification must at least disclose the first segment being bound in order to the fourth segment. However, as such an embodiment is not described in the specification or claims as originally

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filed, the recitation of "a first nucleic acid segment encoding a first polypeptide segment comprising an  $\beta 1\beta 2$  domain of an MHC class II chain molecule" constitutes new matter. Dependent claims 41, 42, 44-46 and 50-54 are included in this ground of rejection, as they all comprise the recitation of the base claim. Applicant should specifically point out the support for any amendments made to the disclosure (See MPEP 714.02 and 2163.06).

### *Conclusion*

4. No claim is allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. *RV*  
Patent Examiner  
January 12, 2004

*Patrick J. Nolan*  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER

*1/12/04*